DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

September 14, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-79

Barrie or James Wilcox, President/Co-President
Wilcox Farms, Inc.
509 McNaught
Roy, Washington 98580

WARNING LETTER

Dear Sirs:

An investigation at your animal feed manufacturing operation located at 509 McNaught, Roy, Washington, conducted by a Food and Drug Administration investigator on August 1,2 and 7, 2001, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured at this facility to be adulterated within the meaning of Section 402(a)(2)(C), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found a failure to establish a written system, including clean out, and flushing procedures, to avoid commingling and cross-contamination of common equipment.

The above is not intended to be an all-inclusive list of deviation from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulations.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response

should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Form FDA 483
Small Entity Compliance Guide